PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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INTELLECTUAL PROPERTY DEPT. (4.3.571)
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PCT

WRITTEN OPINION

(PCT Rule 66)

	Date of Mailing *(day/month/year)* 10 DEC 2004
Applicant' s or agent' s file reference F-8660- PC	REPLY DUE within 2 months/days from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US03/32527	15 October 2003 (15.10.2003)	15 October 2002 (15.10.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): H04N 7/173, 7/16 and US Cl.; 725/133,141,153,74,78,80,82,85,127;348/734,825.09,825.72;398/106,135,107

Applicant

SCIENTIFIC-ATLANTIC, INC.

1. This written opinion is the first (first, etc,) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's o bligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: _____.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer KEN WIEDER Telephone No. 703-305-4800

Form PCT/IPEA/408 (cover sheet)(July 1998)

WRITTEN OPINION

International application No.
PCT/US03/32527

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☒ the description:
pages 1-13, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 14-17, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-8, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*

WRITTEN OPINION

International application No.
PCT/US03/32527

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	6-8	YES
	Claims	1-5 and 9-21	NO
Inventive Step (IS)	Claims	6-8	YES
	Claims	1-5 and 9-21	NO
Industrial Applicability (IA)	Claims	1-21	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS
Please See Continuation Sheet

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:
The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. Citations and Explanations:
Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cuppone et al (Design of Drill Guides for the Thoracic and Cervical Regions of the Spine).

Regarding Claim 1 , Cuppone et al disclose a method for determining the placement of pedicle screws comprising the step of:
determining a trajectory for the placement of a pedicle sctew in a patient with the use of an algorithm, wherein the trajectory is obtained from medical imaging data of the patient's spine, wherein the algorithm is performed on a computer (Abstract; Sections 1 and 2; Table 1, Figure 1. Two cylinders depicted in Figure 1 indicate the drilling depth and trajectories. Based on the patient's CT data the algorithm provides personalized drill guides in a Computer Aided Design (CAO) environment. These guides are designed to fit on the surface of the vedebrae in a unique position and to indicate the pre-planned drill path and drilling length into the pedicle. The guides are manufactured using rapid prototyping technologies, in medically apptoved materials.).

Regarding Claim 2, Cuppone et al disclose the method of Claim 1, wherein the algorithm is implemented with a computer processor (Abstract, lmplementing Computer Aided Design (CAD)).

Regarding Claim 3, Cuppone et al disclose the methöd of Claim 1 further comprising the step of determining the diameter of the pedicle screw (Section 2, third to last paragraph (e.g., 3.2 mm diameter)).

Regarding Claim 4, Cuppone et al disclose the method of Claim 1 further comprising the step of dqtermining the depth for inseding the pedicle screw (Section 2, third to last paragraph (e.g., 60 mm Length)).

Regarding Claim 5, Cuppone et al disclose the method of Claim 1, wherein the algorithm is used to analyze medical imaging data comprising an image of a patient's spine (Abstract, C.T. images).

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Regarding Ciaim 6, the medical imaging data (C.T. images) are inherently intensity-based imaging data.

Regarding Claim 7, Cuppone et al disclose the method of Claim 5, wherein the medical imaging data are chosen from the group consisting of computed tomography data, positron emission tomography data, ultrasound data, and magnetic resonance imaging data (Abstract, C.T. image data).

Regarding Claim 8, Cuppone et al disclose the method of Claim 5 further comprising the step of analyzing the imaging data to determine if the algorithm is compatible with the imaging data (Section 2).

Regarding Claim 9, Cuppone et al further disclose the method of Claim 5. wherein the algorithm further comprises the steps of isolating the bony anatomy of the spine from the imaging data', determining the minimum thickness of a spinal pedicle, the pedicle length, and orientation to the spine (Section 2, second paragraph).

Regarding Claim 10, Cuppone et al disclose thé method of Claim 2, wherein the algorithm is automated (Abstract, Computer Aided Design (CAD)).

Regarding Claim 11, arguments analogous to those presented for Claims 1-4 are applicable to Claim 11 .

Regarding Claim 12, arguments analogous to those presented for Claim 9 are applicable to Claim 12.

Regarding Claim 13, arguments analogous to those presented for Clairù 10 are applicable to Claim 13.

Regarding Claim 14, arguments analogous to those presented for Claim 1 are applicable to Claim 14.

Regarding Claims 15 and 23, arguments analogous to those presented for Claim 10 are applicable to Claims 15 and 23.

Regarding Claim 16, arguments analogous to those presented for Claims 1, 5 and 6 are applicable to Claim 16.

Regarding Claim 17, Cuppone et al further disclose the method of Claim 16, wherein the algorithm further comprises the steps of determining the minimum thickness of the anatomic site, the length of the anatomic site, and orientation to the anatomic site relative to the rest of the body (Section 2).

Regarding Claim 18, arguments analogous to those presented for Claim 3 are applicable to Claim 18.

Regarding Claim 19, arguments analogous to those presented for Claim 4 are applicable to Claim 19.

Regarding Claim 20, arguments analogous to those presented for Claim 7 are applicable to Claim 20.

Regarding Claim 21, arguments analogous to those presented for Claim 8 are applicable to Claim 21.

Claims 24-26 lack an inventive step under PCT Article 33 (3) as being obvious over Spine) in view of Peshkin et al (U.S. 5,799,055)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Regarding Claim 24, arguments analogous to those presented for Claim 1 are applicable to Claim 24.

Cuppone et al further disclose pre-processing the data to ensure compatibility with an algorithm (Abstract. The CT data are pre-processed to incorporate personalized drilling guides to fit perfectly on the patient's vertebrae.);

isolating an anatomic area of interest from the data using a thresholding segmentation defining the boundaries of the anatomic area (Section 2, second paragraph, transferring CT data to MIMICSI; and

calculating the trajectory of an implant at the anatomic area using search calculations based on the anatomic asea and the implant (Table 1), Section 2, second paragraph).

Cuppone et al disclose determining the trajectory of an implant at an anatomic area utilizing CT image data which are three-dimensional image data (Abstract), but do not explicitly disclose defining the boundaries of the anatomic area in three-dimensions.

Peshkin et al disclose a method for permitting effective three-dimensional planning of the trajectories for inseding implants (Column 5, Lines 46-54., Figure 8; Column 13, Lines 32-54).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cuppone et al invention according to the teachings of Peshkin et al tō define the boundaries of the anatomic arèa in three-dimensions because it will provide comprehensive visualization of the anatomic area for accurate insertion of the implants.

Regarding Claim 25, Cuppone et al further disclose the method of Claim 24, wherein the calculations are chosen from the group consisting of minimum anatomic diameter, maximum implant diameter, optimum implant trajectory, maximum length of the anatomic site, optimum length of the implant, and combinations thereof (Section 2).

Regarding Claim 26, Cuppone et al further disclose the method of Claim 25, wherein the calculations are search algorithms that include geometric considerations (Section 2).

----------NEW CITATIONS----------
NONE